

# **DSJ1&2-PR Exh 589**

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**From:** Carl Thorsen <Carl@Thorsen-french.com>  
**Sent:** Thursday, April 03, 2014 7:33 PM  
**To:** Freitas, Kristen; Cosgrove, Jewelyn  
**Subject:** RE: Draft Questions

no problem

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**From:** Freitas, Kristen [mailto:kfreitas@hdmanet.org]  
**Sent:** Thursday, April 03, 2014 3:31 PM  
**To:** Carl Thorsen; Cosgrove, Jewelyn  
**Subject:** RE: Draft Questions

Carl – I would prefer to circulate questions and background directly from HDMA rather than having it forwarded. Hope that makes sense but this is all so sensitive and anxiety levels are high so we need to have some control over how these questions are shared.

Feel free to give me a buzz if you have any questions.

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**From:** Carl Thorsen [mailto:Carl@Thorsen-french.com]  
**Sent:** Thursday, April 03, 2014 3:14 PM  
**To:** Freitas, Kristen; Cosgrove, Jewelyn  
**Subject:** RE: Draft Questions

ok sounds good. possible to get all of these as an HDMA product that we can then forward as needed?

also the attachments i sent. pls scrub my name and source info before they are forwarded as well.

thx

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**From:** Freitas, Kristen [mailto:kfreitas@hdmanet.org]  
**Sent:** Thursday, April 03, 2014 3:08 PM  
**To:** Carl Thorsen; Cosgrove, Jewelyn  
**Subject:** RE: Draft Questions

Carl – Thank you for taking a stab at these. We are in the process of vetting our own questions for John to be prepared to answer and some for us to suggest to the committee. Given our sensitivities to publicly challenging DEA, the questions might be a little strong to come from us so our suggested questions will likely be toned down a bit.

We are working on wording for a question very similar to #2 and typically use the term “suspend orders” rather than artificial/arbitrary limits.

I think the pharmacy questions are good.

Appreciate your help. It is certainly all hands on deck for Monday!

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**From:** Carl Thorsen [<mailto:Carl@Thorsen-french.com>]  
**Sent:** Thursday, April 03, 2014 1:37 PM  
**To:** Cosgrove, Jewelyn; Freitas, Kristen  
**Subject:** FW: Draft Questions

here is what i put together. consider it a rough draft, not vetted what would you think if we clean this up and send from one of you? it can then be forwarded.

lmk thoughts, thanks.

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**From:** Carl Thorsen  
**Sent:** Thursday, April 03, 2014 1:29 PM  
**To:** Carl Thorsen  
**Subject:** Draft Questions

### **Lack of clear regulatory guidance/standards & access to medications for patients who need them**

- 1) The illegal drug trade has very clear laws and we all know that distribution of heroin or methamphetamine is illegal. This type of clarity is very helpful in enforcing the law. With legal pharmaceutical products, what constitutes legal prescribing and dispensing is not as clear. What efforts is DEA engaged in to promulgate clear standards for prescribers, pharmacies, and distributors?
- 2) The DEA Diversion Control Program has two missions: prevent diversion and ensure adequate supply for the legitimate needs of our citizens. I have recently seen stories about patients with serious medical needs being unable to obtain medications. I have also heard that pharmacies cannot get medications because distributors are imposing artificial limits. What are you doing help well-intentioned registrants determine who they can do business with?
- 3) DEA officials have said that we cannot arrest our way out of the pharmaceutical drug abuse problem. We clearly need all DEA registrants to work with DEA to address this problem. As a prosecutor I found that taking a clear and consistent approach to law enforcement promoted cooperation and collaboration with members of the public who wanted to help. I am concerned that there is a lack of clarity for DEA registrants. You have personally signed many immediate suspension orders. What standard do you use when determine whether to issue an immediate suspension order?

### **Comparison to FDA regulatory approach**

See attached Blackburn question from 2012 hearing.

### **Pharmacy perspective**

- 1) If the conduct of a pharmacy is consistent with the public interest, they get a DEA registration, correct? Isn't it your job to take away that registration if a pharmacy is acting inconsistent with the public interest? So, if a legitimate pharmacy is still registered with the DEA and acting according to the public interest, why would they be cut off from providing a necessary service like filling a narcotic prescription? Why is a legitimate pharmacy struggling to meet demand because their distributor won't sell them more than the national average when they are a DEA registered pharmacy?
- (If response is because they don't have the assets to shut down every pharmacy, etc...) If there aren't enough assets, why won't you change your fee structure, as provided for in the law?

- 2) We have been hearing from a pharmacy in our district that their wholesalers are suspending and limiting their orders for controlled substances because they are above a certain threshold amount. Can you describe your expectations of wholesalers?
- 3) When you take an enforcement action against a wholesaler or pharmacy, is there a way to scale enforcement efforts to minimize disruption to legitimate patients?

#### **Enforcement/Prevention**

Given that the severity and tragic consequences of the prescription drug abuse epidemic have risen dramatically over the last decade, how does the DEA measure success in fighting this epidemic? Settlements, sizeable fines, press release, what has all of that really done to prevent prescription drug abuse?

Carlyle P. Thorsen  
Thorsen French Advocacy LLC  
405 1st Street, SE  
Washington, DC 20003  
phone: 202.506.5672  
fax: 202. 506.5676  
[www.thorsen-french.com](http://www.thorsen-french.com)